DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

SEP 08 2009 1952 9 SEP 15 A10:19

Mr. Thomas J. Quinn
411 Tyburn Drive
Wexford, Pennsylvania 15090

Re: Citizen Petition – Docket Number 2007 P-0333

Dear Mr. Quinn,

This letter is in response to the above referenced citizen petition dated August 23, 2007, and filed by the Food and Drug Administration (FDA) on August 27, 2007. Your petition requests strict and immediate enforcement by FDA of 21 CFR 1020.30(g), (h), 1020.33(c), 1040.10(h), and 820.170. In your petition you also request, "a means to calculate Computed Tomography dosage index, dose profile and dosage measurement for a dual tube CT system as prescribed in 21 CFR 1020.30 (c in sequence)." Finally, you request a "public response from the FDA" assuring that FDA will enforce medical device laws. We are denying all of the requests in your petition.

As your request indicates, 21 USC 360hh et seq. give FDA authority over radiation-emitting electronic products, and FDA has promulgated several performance standards for such products pursuant to this authority. The regulations with respect to which you seek enforcement action require manufacturers of certain electronic products to provide certain information to assemblers and users of these products. 21 CFR 1020.30(g), (h), 1020.33(c), 1040.10(h). You also request enforcement of 21 CFR 820.170, which requires manufacturers of devices requiring installation to provide certain information to the persons installing the device. To help manufacturers understand and comply with some of these requirements, FDA issued a guidance document on September 5, 2003, entitled "Guidance for Industry and FDA Staff: Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems," available at http://www.fda.gov/downloads/MedicalDevices/ DeviceRegulationandGuidance/GuidanceDocuments/ucm089810.pdf. CDRH has also posted a letter to manufacturers and assemblers of diagnostic x-ray components and systems reminding them of their obligations, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm128283.htm.

Your first, second, third, and fifth requests ask FDA to enforce these regulations, and medical device laws generally, though you do not provide details related to any specific situation. Requests for the Agency to initiate enforcement actions are not within the scope of FDA's citizen petition procedures. See 21 CFR 10.30(k). In general, decisions with respect to initiating enforcement actions are made on a case-by-case basis and are within the discretion of the Agency. When concerns about individual manufacturer compliance with these regulations arise,

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FDA carefully reviews the concerns and, as appropriate, seeks further information, e.g., through inspections. In some cases, no violation will be identified. When there has been a violation, sometimes the issues brought to our attention will be resolved successfully through voluntary compliance; in other instances FDA will initiate an enforcement action.

Your fourth request asks the agency to provide a means to calculate the Computed Tomography Dose Index (CTDI), dose profile, and dose measurement for a dual tube CT system, "as prescribed in 21 CFR 1020.30 (c in sequence)"; it appears you meant to cite to 21 CFR 1020.33(c). The means to calculate CTDI and the meaning of "dose profile" and other terms related to dose measurement are provided at 21 CFR 1020.33(b). FDA has also issued guidance explaining an acceptable alternative method of calculating CTDI. See "Guidance for Industry, FDA Staff, and Third Parties: Provision for Alternate Measure of the Computed Tomography Dose Index (CTDI) to Assure Compliance with the Dose Information Requirements of the Federal Performance Standard for Computed Tomography," (October 20, 2006), available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094381.pdf.

The definitions and dose information requirements at 21 CFR 1020.33 are not limited to single tube CT systems or dependent on the number of tubes in the CT system. There is no difference between calculating the CTDI, dose profile, or other measures required under 21 CFR 1020.33(c) for a single tube CT system and calculating such for a dual tube CT system. There would be no safety benefits gained from providing a different means to calculate these measures for dual tube CT systems.

In your petition, you also suggest that unnecessary deaths are occurring due to the improper installation of computed tomography (CT) scanners and perhaps other radiation-emitting devices; however, you did not provide specific details related to any adverse events. FDA monitors adverse events through its Medical Device Reporting (MDR) system and works proactively with hospitals to identify injuries, deaths, and significant failures of medical devices. When such problems are identified, FDA takes action to address them and notifies the public and health care communities, as appropriate. FDA is not aware of any reports of deaths from the improper installations of CT scanners or other radiation-emitting devices.

If you have any questions regarding this response, please contact Myrna Hanna of our Regulation Staff at (301) 796-5739.

Sincerely yours,

David J. Horowitz, J.D.
Assistant Commissioner for Policy